REMARKS/ARGUMENTS

Claims 237-280 are pending, whereby claims 237, 254 and 273 are independent. Applicant respectfully submits that no new matter has been added by way of this amendment. No fees are believed due.

Support for the new claims can be found throughout the specification and claims as originally filed and in the priority documents for this application. Particular examples of support for the new claims are provided in the following table.

Claim	Illustrative Support
237	Page 25, lines 25-27; Page 26, lines 5-6; Page 31, lines 10-14; Page 41, lines 13-16; Page 42, line 10 to Page 43, line 13; Examples I.A, I.B1, I.B3, I.C1, I.C3, I.D1, I.D3, I.F1, I.F3, I.G1 and I.G3
238	Page 31, lines 8-10
239	Page 42, line 10 to Page 43, line 13; Example I.A; Examples I.B1-B3; Examples I.C1-C3; Examples I.D1-D3; Examples I.F-F3, Example I.G1-G3
240	Page 31, lines 8-10
241	Examples I.A, I.B1, I.B3, I.C1, I.C3, I.D1, I.D3, I.F1, I.F3, I.G1 and I.G3
242	Page 22, lines 16-27
243	Page 31, lines 10-14
244	Page 31, lines 10-14
245	Page 42, line 10 to Page 43, line 13
246	Page 24, line 7 to Page 25, line 7
247	Page 24, line 7 to Page 25, line 7
248	Page 25, line 25 to Page 26, line 7
249	Page 25, lines 19-20
250	Page 47, line 19
251	Page 25, lines 20-21
252	Page 41, lines 11-12
253	Page 22, lines 16-27
254	Page 20, line 16 to Page 21, line 8; Page 25, lines 25-27; Page 31, lines 10-14; Examples I.A, I.B1-B3, I.C1-C3, I.D1-D3, I.F1-F3 and I.G1-I.G3

Claim	Illustrative Support
255	Page 31, lines 8-10
256	Page 42, line 10 to Page 43, line 13; Examples I.A, I.B1, I.B3, I.C1, I.C3, I.D1, I.D3, I.F1, I.F3, I.G1 and I.G3
257	Page 31, lines 8-10
258	Examples I.A, I.B1-B3, I.C1-C3, I.D1-D3, I.F1-F3 and I.G1-I.G3
259	Page 22, lines 16-27
260	Page 31, lines 10-14
261	Page 31, lines 10-14
262	Page 42, line 10 to Page 43, line 13
263	Page 24, line 7 to Page 25, line 7
264	Page 24, line 7 to Page 25, line 7
265	Page 26, lines 5-6
266	Page 25, lines 19-20
267	Page 47, line19
268	Page 25, lines 20-21
269	Page 41, lines 11-12
270	Page 22, lines 16-27
271	Page 44, lines 7-14
272	Page 44, lines 7-14
273	Page 31, lines 10-14; Page 25, line 7-24
274	Page 31, lines 10-14
275	Page 31, lines 10-14
276	Page 31, lines 8-10
277	Page 31, lines 8-10
278	Page 31, lines 8-10
279	Page 25, line 25 to Page 26, line 8
280	Page 44, lines 7-14

I. THE WRITTEN DESCRIPTION REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, SHOULD BE WITHDRAWN.

The Final Office Action rejected claim 151 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement for adding new matter. Applicant respectfully requests that this rejection be withdrawn in light of the current amendments, made without admitting or conceding in any manner that the rejected claims fail to comply with 35 U.S.C. § 112, first paragraph and solely to expedite the prosecution of the present application.

Moreover, as demonstrated above, the pending claims are supported by the specification as filed. According to the Federal Circuit, "[i]f a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if not every nuance of the claims is explicitly described in the specification, then the adequate written description requirement is met." *In re Alton*, 76 F.3d 1168 (Fed. Cir. 1996). Furthermore, "ranges found in an applicant's claims need not correspond exactly to those disclosed in a parent application; the issue is whether one skilled in the art could derive the claimed ranges from the parent's disclosure." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991). Below is a table that provides the weight percent ("wt-%") and amounts of sodium bicarbonate and disintegrant for Example I.A; Examples I.B1 and I.B3; Examples I.C1 and I.C3; Examples I.D1 and I.D3; Examples I.F and I.F3; and Examples I.G1 and I.G3.

Example	Disintegrant (wt-%)	Sodium Bicarbonate (wt-%)
I.A.	66 mg (3.8 wt-%)	975 mg (56 wt-%)
I.B1.	12 mg (1.8 wt-%)	250 mg (37 wt-%)
I.B3.	12 mg (1.3 wt-%)	750 mg (84 wt-%)
I.C1.	12 mg (1.7 wt-%)	250 mg (36 wt-%)
I.C3.	12 mg (1.3 wt-%)	750 mg (83 wt-%)
I.D1.	12 mg (1.3 wt-%)	500 mg (54 wt-%)
I.D3.	12 mg (1.4 wt-%)	700 mg (84 wt-%)
I.F1.	12 mg (1.9 wt-%)	250 mg (39 wt-%)
I.F3.	12 mg (1.6 wt-%)	700 mg (92 wt-%)
I.G1.	12 mg (1.5 wt-%)	400 mg (48 wt-%)
I.G3.	12 mg (1.5 wt-%)	750 mg (97 wt-%)

As discussed above, additional support for the claimed ranges can be found throughout the specification and examples as filed. Thus, the pending claims meet the written description requirement under 35 U.S.C. § 112, first paragraph.

II. THE REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH, SHOULD BE WITHDRAWN.

The Final Office Action dated June 13, 2007 rejected claims 151-154, 156-159, 163, 165-170, 172-178, 180 and 182-236 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Without admitting or conceding in any manner to the appropriateness of this rejection and solely to expedite the prosecution of pending claims 237-280, claims 151-154, 156-159, 163, 165-170, 172-178, 180 and 182-236 have been cancelled.

In light of the current amendments, Applicant respectfully requests withdrawal of this rejection.

III. THE ENABLEMENT REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, SHOULD BE WITHDRAWN.

The Final Office Action dated June 13, 2007 rejected claims 151-154, 156-159, 163, 165-170, 172-178, 180 and 182-236 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Specifically, the Final Office Action dated June 13, 2007 "recommend[s] that the composition be claimed as what it is not what it does." Applicant respectfully requests that this rejection be withdrawn in light of the current amendments, made without admitting or conceding in any manner that the rejected claims fail to comply with 35 U.S.C. § 112, first paragraph and solely to expedite the prosecution of the present application.

IV. THE REJECTION UNDER 35 U.S.C. 102(b) SHOULD BE WITHDRAWN.

The Final Office Action maintained the rejection of claims 151-154, 156-159, 163, 165-170, 172 and 175 under 35 U.S.C. § 102(b) as being anticipated by WO 97-25066 ("Depui") or JP 05-255088 ("Oishi") supplemented with Horowitz. Applicant respectfully traverses this rejection and hereby incorporates by reference in entirety its response dated March 21, 2007 to the Office Action dated December 21, 2007.

M.P.E.P. § 2131 provides that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as contained in the ... claim." *Richardson v. Suziki Motor Co.*, 868 F.2d 1226,

1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). Lastly, "the elements must be arranged as required by the claim..." *In re Bond*, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990).

The pending claims are directed to solid dosage forms comprising specific amounts of non-enteric coated omeprazole, sodium bicarbonate and, in the case of pending claims 237-272, specific amounts of a disintegrant. Applicant respectfully submits that none of Depui, Oishi or Horowitz discloses each and every element of Applicant's pending claims and therefore cannot anticipate said claims. Moreover, the claims depending from independent claims 237, 254 and 273 add additional limitations not taught by the references relied on by the Examiner.

Oishi discloses enteric coated preparations having a core containing a benzimidazole compound and small amounts of aluminum hydroxide-sodium bicarbonate co-precipitate surrounded by 1-2 layers of undercoating with an enteric coating thereupon. Oishi does not disclose a finished dosage form having non-enteric coated omeprazole. While Oishi does disclose an intermediate core that is not enteric coated, the disclosed core is not a finished dosage form. Oishi expressly states that such a core is coated with an enteric coating agent. (See *e.g.* page 2). Therefore, each and every element of Applicant's claims are not disclosed in Oishi.

Depui also fails to teach each limitation of Applicant's pending claims. First, Depui states that its enteric coated formulations do not disintegrate in the stomach. Depui specifically states that its enteric coating makes "the pellets of the dosage form ***insoluble in acidic media***, but disintegrating/dissolving in near neutral to alkaline media such as, for instance the liquids present in the proximal part of the small intestine, where dissolution of the proton pump inhibitor is desired" (emphasis added). Depui at p. 20, ll. 25-28. Additionally, Depui teaches that the "enteric coating layer(s) covering the individual units of the acid susceptible proton pump inhibitor ("PPI") has properties such that the compression of the units into a tablet does not significantly affect the acid resistance of the individually enteric coating layered units." *Id.* at p. 5, ll. 19-22. Moreover, Depui states:

> If the enteric coating layer does not withstand the compression of the pellets into a tablet the susceptible active substance will be destroyed upon administration by penetrating acidic gastric juice, *i.e.*, the acid resistance of the enteric coating layer of the pellets will not be sufficient in the tablet after compression.

Id. at p. 4, ll. 8-11. As discussed above, Applicant's claims contain non-enteric coated omeprazole. Depui not only fails to teach this limitation of the pending claims, but actually teaches against it:

> Some gastric acid suppressing agents, such as proton pump inhibitors, are susceptible to degradation/transformation in acid reacting and neutral media. In respect of the stability properties, ***it is obvious*** that one of the active substances being a proton pump inhibitor ***must*** be protected from contact with acid gastric juice by an enteric coating layer.

Depui at p. 3, ll. 25-28 (emphasis added).

Moreover, the combination of Horowitz with Depui is improper. First, Horowitz employs about 4,032 mg of sodium bicarbonate per 90 mg of omeprazole—an amount of buffer that could not practically be used in a solid dosage form. Depui, on the other hand only discloses a total buffering agent to total PPI weight ratio of up to about 2:1 (or 180 mg buffer per 90 mg omeprazole). To assume that 180 mg of sodium bicarbonate would provide the same protection of a PPI in gastric acid as 4,032 mg is speculative. Therefore, Horowitz cannot be used to demonstrate the pharmacokinetic characteristics of Depui's enteric coated compositions.

Second, it is well known that a given drug substance will have different absorption rates and times of onset depending on the dosage form and excipients, and that these differences are a function of both the formulation and the route of administration. *See e.g.* Ansel et al., Pharmaceutical Dosage Forms and Drug Delivery Systems, Williams & Wilkins, 1995, pp. 77 ("An individual drug substance may be formulated into multiple dosage forms which result in different drug absorption rates and times of onset, peak, and duration of action."). This is because, for example, a solid dosage form must first disintegrate and then dissolve before the PPI is released, and only after this occurs can the PPI be absorbed (assuming that it has not been degraded by stomach acid). Accordingly, Horowitz's liquid disclosure provides no meaningful evidence relevant to the pharmacokinetic performance of Depui's solid dosage form.

For the foregoing reasons, Applicant submits that pending claims 237-280 are patentable over Depui, Oishi and Horowitz.

V. THE REJECTION UNDER 35 U.S.C. 103(a) SHOULD BE WITHDRAWN.

The Office Action of June 13, 2007, maintained the rejection of record under 35 U.S.C. § 103(a) over U.S. Patent No. 4,613,497 ("Chavkin") in view of U.S. Patent No. 4,508,905

("Junggren") or Depui or Oishi supplemented with Horowitz further in view of Parachini, *Two New Drug Treatments Offer Hope to Ulcer Sufferers*, Los Angeles Times, Los Angeles, CA, August 30, 1988, page 1 ("Parachini") and Waring, *Questions and Answers about Medication and GERD*, DIGESTIVE HEALTHCARE OF GEORGIA; available at: http://www.aboutgerd.org/MedQA.html ("Waring").

Applicant respectfully traverses the rejection and requests that the rejection be withdrawn in light of the arguments set forth previously and the present amendments to the claims. Again, Applicant incorporates by reference in entirety the arguments advanced in its response dated March 21, 2007 to the Office Action dated December 21, 2007.

Moreover, the claims now pending are directed to solid dosage forms comprising specific amounts of non-enteric coated omeprazole, sodium bicarbonate and, in the case of pending claims 237-272, specific amounts of a disintegrant. Applicant respectfully submits that none of obviousness references relied on by the Examiner teach or suggest each and every element of Applicant's pending claims and therefore cannot render obvious these claims. Moreover, the claims depending from independent claims 237, 254 and 273 add additional limitations not taught or suggested by the obviousness references relied on by the Examiner.

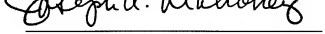
For the foregoing reasons, Applicant submits that pending claims 237-280 are patentable over Chavkin, Junggren, Depui, Oishi, Horowitz, Parachini and Waring alone or in combination with one another.

Conclusion

For at least the foregoing reasons, it is respectfully submitted that claims 237-280 are in condition for allowance. Early and favorable consideration is respectfully requested, and the Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution. Further, none of Applicant's amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicant reserves all rights to pursue any such subject matter in this or a related patent application.

Kindly contact the undersigned with any questions or to otherwise expedite prosecution.

Respectfully submitted,



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